UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 29, 2024

DAY ONE BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40431**	**83-2415215**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2000 Sierra Point Parkway, Suite 501
Brisbane, California **94005**
(Address of principal executive offices) **(Zip Code)**

Registrant's telephone number, including area code: (650) 484-0899

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	DAWN	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry into a Material Definitive Agreement.

On May 29, 2024, Day One Biopharmaceuticals, Inc. (the "Company") entered into an asset purchase agreement (the "PRV Transfer Agreement"), pursuant to which the Company agreed to sell a Rare Pediatric Disease Priority Review Voucher ("PRV") for $108.0 million, payable in cash, upon the closing of the sale, which occurred simultaneously with the parties entering into the PRV Transfer Agreement. As part of the transaction, $8.1 million of the total consideration received from the sale of the PRV pursuant to the PRV Transfer Agreement will be paid to Viracta Therapeutics, Inc. ("Viracta") pursuant to the Company's License Agreement with Viracta, dated December 16, 2019, as amended.

The Company was awarded the PRV under a U.S. Food and Drug Administration ("FDA") program intended to encourage the development of certain rare pediatric disease product applications. The Company received the PRV when OJEMDA™ (tovorafenib) drug product was approved by the FDA on April 23, 2024 for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.

The PRV Transfer Agreement contains customary representations, warranties, covenants and indemnification provisions subject to certain limitations.

The foregoing description of the PRV Transfer Agreement does not purport to be complete and is qualified in its entirety by the text of the PRV Transfer Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2024.

Item 2.01. Completion of Acquisition or Disposition of Assets.

The information contained above in Item 1.01 is hereby incorporated by reference into this Item 2.01.

Item 7.01 Regulation FD Disclosure.

On May 30, 2024, the Company issued a press release pursuant to which it announced that it had entered into the PRV Transfer Agreement. In addition, on May 30, 2024, the Company updated its corporate presentation.

Copies of the press release and updated presentation are attached as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K.

The information furnished in this Item 7.01, including Exhibits 99.1 and 99.2 to this Current Report on Form 8-K, shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Current Report on Form 8-K and in the accompanying Exhibits 99.1 and 99.2 shall not be incorporated by reference into any other filing under the Securities Exchange Act of 1934, as amended, or under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release.
99.2	Corporate Presentation.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DAY ONE BIOPHARMACEUTICALS, INC.

Date: May 30, 2024

By: /s/ Charles N. York II, M.B.A.
Charles N. York II, M.B.A.
Chief Operating Officer and Chief Financial Officer

Day One Announces Sale of Priority Review Voucher for $108 Million

BRISBANE, Calif., May 30, 2024 — Day One Biopharmaceuticals (Nasdaq: DAWN) ("Day One" or the "Company"), a commercial-stage biopharmaceutical company dedicated to developing and commercializing targeted therapies for people of all ages with life-threatening diseases, today announced it sold its Priority Review Voucher ("PRV") for $108 million to an undisclosed buyer. The Company was awarded the PRV following the U.S. Food and Drug Administration ("FDA") accelerated approval of OJEMDA™ (tovorafenib).

"The sale of the PRV delivers true non-dilutive capital to Day One and further strengthens our balance sheet as we continue executing on the launch of OJEMDA and investing in clinical development opportunities for children and adults living with cancer," said Charles York II, chief operating and financial officer of Day One.

Under the Rare Pediatric Disease Priority Review Voucher Program, FDA awards PRVs to sponsors of rare pediatric disease product applications that meet certain criteria. The program is intended to encourage development of new drugs and biologics for the prevention and treatment of rare diseases. A PRV can be redeemed to receive priority review of a subsequent marketing application for a different product, sold or transferred.

As part of the transaction, $8.1 million of the total consideration received from the sale of the PRV will be paid to Viracta Therapeutics, Inc. ("Viracta") to fully satisfy PRV related obligations of the Company's license agreement with Viracta, dated December 16, 2019, as amended.

About Day One Biopharmaceuticals

Day One Biopharmaceuticals is a commercial-stage biopharmaceutical company that believes when it comes to pediatric cancer, we can do better. The Company was founded to address a critical unmet need: the dire lack of therapeutic development in pediatric cancer. Inspired by "The Day One Talk" that physicians have with patients and their families about an initial cancer diagnosis and treatment plan, Day One aims to re-envision cancer drug development and redefine what's possible for all people living with cancer—regardless of age—starting from Day One.

Day One partners with leading clinical oncologists, families, and scientists to identify, acquire, and develop important targeted cancer treatments. The Company's pipeline includes tovorafenib (OJEMDA™) and pimasertib.

Day One is based in Brisbane, California. For more information, please visit www.dayonebio.com or find the Company on LinkedIn or X.

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: Day One's plans to develop cancer therapies, expectations from current clinical trials, and the ability of tovorafenib to treat pLGG or related indications.

Statements including words such as “believe,” “plan,” “continue,” “expect,” “will,” “develop,” “signal,” “potential,” or “ongoing” and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements.

Forward-looking statements are subject to risks and uncertainties that may cause Day One’s actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties in this press release and other risks set forth in our filings with the Securities and Exchange Commission, including Day One’s ability to develop, obtain regulatory approval for or commercialize any product candidate, Day One’s ability to protect intellectual property, the potential impact of global business or macroeconomic conditions, including as a result of inflation, rising interest rates, instability in the global banking system, geopolitical conflicts and the sufficiency of Day One’s cash, cash equivalents and investments to fund its operations. These forward-looking statements speak only as of the date hereof and Day One specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

DAY ONE MEDIA
Laura Cooper, Head of Communications
media@dayonebio.com

DAY ONE INVESTORS
LifeSci Advisors, PJ Kelleher
pkelleher@lifesciadvisors.com

#####

Exhibit 99.2

Day One Biopharmaceuticals

Targeted Therapies for People of All Ages

May 2024

Disclaimer

This presentation and the accompanying oral commentary contain forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expect," "plan," anticipate," "believe," "estimate," "predict," "intend," "potential," "would," "continue," "ongoing" or the negative of these terms or other comparable terminology. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our future financial performance, including the sufficiency of our cash, cash equivalents and short-term investments to fund our operations, business plans and objectives, timing and success of our planned nonclinical and clinical development activities, the results of any of our strategic collaborations, including the potential achievement of milestones and provision of royalty payments thereunder, timing and results of nonclinical studies and clinical trials, efficacy and safety profiles of our products and product candidates, the ability of tovorafenib to treat pediatric low-grade glioma (pLGG) or related indications, the potential therapeutic benefits and economic value of our products and product candidates, potential growth opportunities, competitive position, industry environment and potential market opportunities, our ability to protect intellectual property and the impact of global business or macroeconomic conditions, including as a result of inflation, changing interest rates, cybersecurity incidents, potential instability in the global banking system, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto and global regional conflicts, on our business and operations.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. These factors, together with those that are described under the heading "Risk Factors" contained in our most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission ("SEC") and other documents we file from time to time with the SEC, may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this presentation, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

Cancer Therapies for People of All Ages

Day One BIOPHARMACEUTICALS

Our Approach

- Develop medicines for genomically-defined cancers
- Establish first-in-class position through rapid registration pathways
- Expand to adolescent and adult populations in parallel and pursue those opportunities with the same commitment we do for children

Nasdaq: DAWN | IPO: 2021 | Founded: 2018 | Financial Position: Runway into 2026

Our Pipeline

Product Candidate	Therapeutic Area	Preclinical	Phase 1	Phase 2	Phase 3/ Registrational	Approved	Recent & Anticipated Milestones
Tovorafenib Type II RAF Inhibitor OJEMDA brand name in U.S.[1]	BRAF-altered Relapsed pLGG	FIREFLY-1 (pivotal Phase 2)				ojemda® (tovorafenib)	**FDA approval:** April 2024
	Frontline RAF-altered pLGG	FIREFLY-2 (pivotal Phase 3)					**First patient dosed:** March 2023
Pimasertib MEK 1/2 Inhibitor	MAPK-altered solid tumors[†] (Combo w/ tovorafenib)	FIREFLIGHT-1[††]					**Recommended Phase 2 dose & schedule expected:** 2H 2024
VRK1 Program VRK1 Inhibitor	Pediatric and adult cancers						**In-licensed[§]:** August 2023

[1] OJEMDA has received accelerated approval by the U.S. Food and Drug Administration. [†] Pimasertib Phase 1 dose escalation and expansion trial previously completed. [††] Includes patients ≥12 years of age. [§] Research collaboration and license agreement with Sprint Bioscience AB for exclusive worldwide rights to a research-stage program targeting VRK1. pLGG, pediatric low-grade glioma.
The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established.

Day One BIOPHARMACEUTICALS

OJEMDA™ (tovorafenib)

Relapsed or Refractory BRAF-altered pLGG

OJEMDA Now Approved In The U.S.

ojemda™
(tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

OJEMDA is the **first and only FDA Approved therapy** for the treatment of pediatric patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation

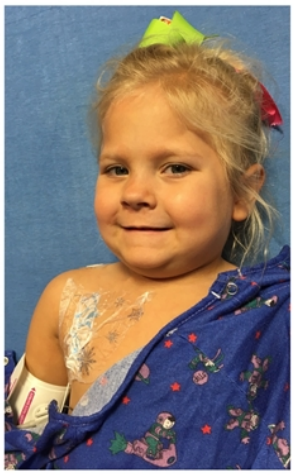
*This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

Day One BIOPHARMACEUTICALS

pLGG Impact On Patients' Lives

Lily was diagnosed with an operable brain tumor at 5 months of age






Pediatric Low-Grade Glioma: The Most Common Type Of Brain Tumor In Children

pLGGs are chronic and relentless, with patients suffering profound tumor and treatment-associated morbidity that can impact their life trajectory over the long term[1]

A Serious and Life-Threatening Disease

- For the majority of pLGG patients in the relapsed setting, there is no standard of care and no approved therapies
- Up to 75% of pLGGs have a BRAF alteration*, of those ~80% are BRAF fusions and ~20% are BRAF V600 mutations[2-6]
- Despite surgery playing a significant role in treatment, the vast majority of patients still require systemic therapy[7,8]
- Due to high rate of disease recurrence, most patients will undergo multiple lines of systemic therapy over the course of their disease

*Incidence of BRAF alterations varies across pLGG subtypes. [1] Sievert AJ, Fisher MJ. Pediatric low-grade gliomas. *J Child Neurol.* 2009;24(11):1397-1408. doi:10.1177/0883073809342005. [2] Penman CL et al. *Front Oncol.* 2015;5:54. [3] Cohen AR., *N Engl J Med.* 2020;386(20):1922-1931. [4] Lassaletta A, et al. *J Clin Oncol.* 2017;35(25):2934-2941. [5] Faulkner C, et al. J Neuropathol Exp Neurol. 2015;74(9):867-872. [6] Packer RJ, et al. Neuro Oncol. 2017;19(6):750-761. [7] Ostrum QT et al., Neuro Oncol. 2015; 16(Suppl 10):x1-x36; [8] De Blank P. et al., Curr Opin Pediatr. 2019 Feb; 31(1):21-27.

Day One BIOPHARMACEUTICALS

Conventional Treatments Can Be Disruptive To Childhood And Can Have Significant Long-Term Consequences

Surgery

- Significant recovery times
- Risks of complications
- Resection may be limited by location of tumor
- Potential for functional deficits based on location of tumor and extent of resection

Chemotherapy

- Requirement for indwelling catheter and weekly infusions
- Risk of neutropenia, hypersensitivity reactions, nausea and vomiting and peripheral neuropathy

Radiation

- Risk of secondary malignancy
- Risk of malignant transformation
- Risk of vascular proliferation and stroke
- Neurocognitive impact, depending on location of tumor and radiation field

Goal of therapy is to control the tumor, minimize the burden of surgery, chemotherapy, and radiation, and reduce the risk of life-long treatment and disease-related effects

Source: 1. Heitzer AM, Raghubar K, Ris MD, et al. Neuropsychological functioning following surgery for pediatric low-grade glioma: a prospective longitudinal study. J Neurosurg Pediatr. 2019;1-9. doi:10.3171/2019.9.PEDS19357. 2. Bryant R. Managing side effects of childhood cancer treatment. J Pediatr Nurs. 2003;18(2):113-125. doi:10.1053/jpdn.2003.11. 3. Zahnreich S, Schmidberger H. Childhood cancer: occurrence, treatment and risk of second primary malignancies. Cancers (Basel). 2021;13(11):2607. doi:10.3390/cancers/13112607. 4. National Cancer Institute. Fertility issues in girls and women with cancer. http://www.cancer.gov. Accessed June 13, 2022. 5. Alessi I., Caroleo A.M., de Palma L., Mastronuzzi A., Pro S., Colafati G.S., Boni A., Della Vecchia N., Velardi M., Evangelisti M., et al. Short and Long-Term Toxicity in Pediatric Cancer Treatment: Central Nervous System Damage. Cancers. 2022;14:1540. doi: 10.3390/cancers14061540.

Overview U.S. Prescribing Information For OJEMDA™ (tovorafenib)

Available in tablet formulation and pediatric-friendly powder for oral suspension

INDICATION

OJEMDA is indicated for the treatment of pediatric patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation

RECOMMENDED DOSE

380 mg/m^2 administered orally once weekly (not to exceed a dose of 600mg once weekly); OJEMDA can be taken with or without food

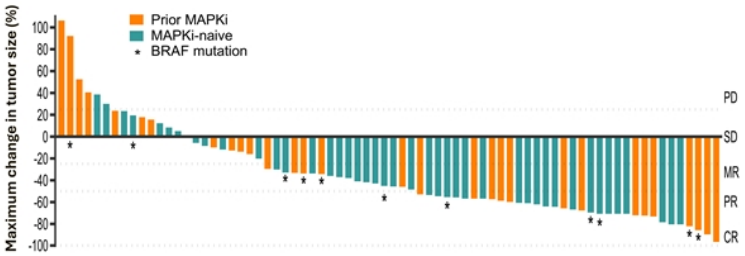
For full prescribing information, visit dayonebio.com

*This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

Day One BIOPHARMACEUTICALS

Efficacy Summary From OJEMDA™ (tovorafenib) Prescribing Information

51% **Overall response rate (RAPNO-LGG) in 76 evaluable patients**



	RAPNO-LGG		
Response (IRC)	n	n (%)	95% CI
ORR, n (%)	**76**	**39 (51)**	**40-63**
BRAF fusion or rearrangement	64	33 (52)	39-64
BRAF V600 mutation	12	6 (50)	21-79
Prior MAPKi use	45	22 (49)	31-64
MAPKi-naïve	31	17 (55)	36-73
Median DOR, months	**39**	**13.8**	**11.3-NR†**
Median TTR, months	**39**	**5.3**	
Range		1.6-11.2	

June 5, 2023 data cutoff. CI, confidence interval; DOR, duration of response; IRC, independent radiology review committee; LGG, low-grade glioma; NR, not reached; ORR, overall response rate; RAPNO, Response Assessment in Pediatric Neuro-Oncology; TTR, time to response; CR, complete response; PR, partial response; MR, minor response; SD, stable disease; PD, progressive disease. † As of the data cutoff, 66% remain on tovorafenib.

Safety Summary From OJEMDA™ (tovorafenib) Prescribing Information

Warnings and Precautions

- Hemorrhage
- Skin toxicity, including photosensitivity
- Hepatotoxicity
- Effect on growth
- Embryo-fetal toxicity
- Use in NF1- associated tumors

No boxed warnings or contraindications

	TEAEs (≥ 30% of patients [n=137])	
Preferred Term, n (%)	**Any Grade**	**Grade ≥3**
Any AE	137 (100)	86 (63)
Hair color changes	104 (76)	0
Anemia	81 (59)	15 (11)
Elevated CPK	80 (58)	16 (12)
Fatigue	76 (55)	6 (4)
Vomiting	68 (50)	6 (4)
Hypophosphatemia	64 (47)	0
Headache	61 (45)	2 (1)
Maculo-papular rash	60 (44)	11 (8)
Pyrexia	53 (39)	5 (4)
Dry skin	49 (36)	0
Elevated LDH	48 (35)	0
Increased AST	47 (34)	4 (3)
Constipation	45 (33)	0
Nausea	45 (33)	0
Upper RTI	43 (31)	2 (1)
Dermatitis acneiform	42 (31)	1 (1)
Epistaxis	42 (31)	1 (1)

June 5, 2023 data cutoff. OJEMDA safety data (n=137). Treatment-emergent AEs ≥20% any grade in arms 1 & 2. AE, adverse event; AST, aspartate aminotransferase; CPK, creatine phosphokinase; LDH, lactate dehydrogenase; RTI, respiratory tract infection; TEAEs, treatment-emergent adverse events.

Estimated *BRAF*-Altered pLGG Patient Population In The U.S.

Up to 75% of pLGG cases are BRAF-altered[7-14]

Incidence of BRAF alterations varies across pLGG subtypes

~80% **of these cases have BRAF fusion, primarily KIAA1549-BRAF†**

~20% of these cases have BRAF point mutations, primarily BRAF V600††

[1] Selt F, van Tilburg CM, Bison B, et al. Response to trametinib treatment in progressive pediatric low-grade glioma patients. J Neurooncol. 2020;149(3):499-510. doi:10.1007/s11060-020-03640-3. [2] Ryall S, Tabori U, Hawkins C. Pediatric low-grade glioma in the era of molecular diagnostics. Acta Neuropathol Commun. 2020;8(1):30. doi:10.1186/s40478-020-00902-z. [3] SEER US complete prevalence counts of patients aged under 25 with Brain and Other Nervous Systems tumors as of January 1, 2017. [4] CBTRUS, Qaddoumi et al 2009, Schreck et al 2019, ClearView Analysis. [5] US Census. Estimated annual incidence, estimated prevalence, and estimated recurrent/progressive total addressable patient population are Day One calculations based on publicly available data. [6] Source: Internal market research conducted by EpidStrategies, A Division of ToxStrategies, Inc. on behalf of Day One. [7] Ryall S, et al. *Acta Neuropathol Commun.* 2020;8(1):30. [8] Behling F, et al. *Cancers (Basel).* 2019;11(6):794. [9] Penman CL, et al. *Front Oncol.* 2015;5:54. [10] Packer RJ, et al. *Neuro Oncol.* 2017;19(6):750-761. [11] Cohen AR, et al. *N Engl J Med.* 2022;386(20):1922-1931. [12] Ryall S, et al. *J Neuropathol Exp Neurol.* 2017;76(7):562-570. [13] Lassaletta A, et al. *J Clin Oncol.* 2017;35(25):2934-2941. [14] Faulkner C, et al. *J Neuropathol Exp Neurol.* 2015;74(9):867-872. * The estimated addressable pool of recurrent or progressive pLGG patients is based on progression free survival curves modeled from published literature. † Predominantly seen in pilocytic astrocytomas. †† May vary across pLGG subtypes. BRAF, V-Raf murine sarcoma viral oncogene homolog B; MAPK, mitogen-activated protein kinase; pLGG, pediatric low-grade glioma.

Day One BIOPHARMACEUTICALS

What Physicians & Caregivers Are Looking For In A Therapy

What HCP's are Seeking

Effective in stopping or shrinking tumors
Manageable safety profile
Minimal disruption to child's life

"The goal is not interfering with the child's life."
– Ped Onc, Chicago Ad Board

What Caregivers are Seeking

Live as normal of a childhood as possible
Minimal impact from the disease
Minimal disruption to child's life

"Our time with our kids is precious and not guaranteed, so the less time with meds and doctors the better."
– Caregiver for a child under 5 yrs

Product Profile Aligns With What Physicians Are Looking For In A Therapy

ojemda™ (tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

Efficacy	Meaningful tumor stabilization or shrinkage may be possible with OJEMDA. In the clinical trial: • 51% of children experienced tumor shrinkage by at least 25% • 82% of children saw their tumors shrink or remain stable
Safety	Generally well-tolerated therapy, with 9 out of 10 patients staying on treatment in the clinical trial Most common grade 3 / 4 adverse events include: anemia, elevated CPK, maculo-papular rash, fatigue & vomiting
Dosing	Once-weekly, taken with or without food conveniently from home can mean fewer daily interruptions

OJEMDA is indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion, rearrangement, or BRAF V600 mutation.

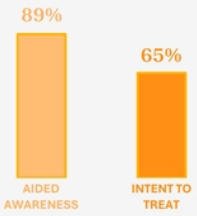
Data from Pivotal Phase 2 FIREFLY-1 trial.

Comprehensive Approach For A Successful Launch

ojemda™ (tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

Physicians

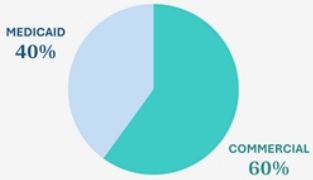
Objective: Establish OJEMDA™ as 1st choice in relapsed / refractory *BRAF*-altered pLGG patients



- Dedicated & experienced sales team to engage HCPs

Payers

Objective: Rapidly establish coverage



- Pre-launch engagement to establish Day One & provide background information
- Plans in place for rapid engagement post-approval

Patients & Families

Objective: Provide a positive & supportive experience when initiating therapy

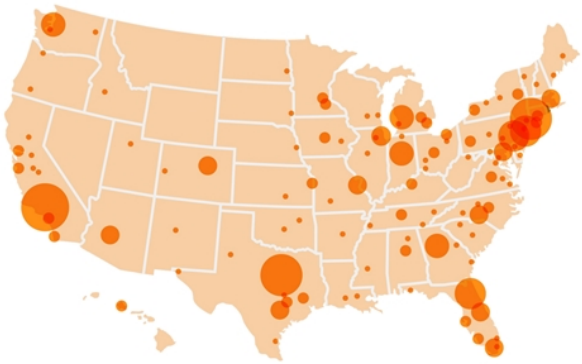
Biologics By McKesson | Onco360® ONCOLOGY PHARMACY

- SP distribution enables consistent patient experience
- Comprehensive patient support programs address patient needs and accelerates access to drug

Targeted Launch With Highly Experienced Field Team

ojemda™ (tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

Targeting ~200 centers where 90% of pLGG patients receive treatment



Deep oncology experience with relationships at top-tier accounts

18 Account Managers fully-dedicated to OJEMDA

Average experience:

13 years of oncology

4 years of rare disease

2 years of pediatric oncology clinical experience

Institutional experience and existing relationships with key accounts

Day One BIOPHARMACEUTICALS

Patient Support Program Supporting Access

ojemda™ (tovorafenib)
100 mg tablets
25 mg/mL for oral suspension

EveryDay Support.

FROM DAY ONE

Day One BIOPHARMACEUTICALS

FIREFLY-2 / LOGGIC

Pivotal Phase 3 Trial of Tovorafenib in Frontline pLGG

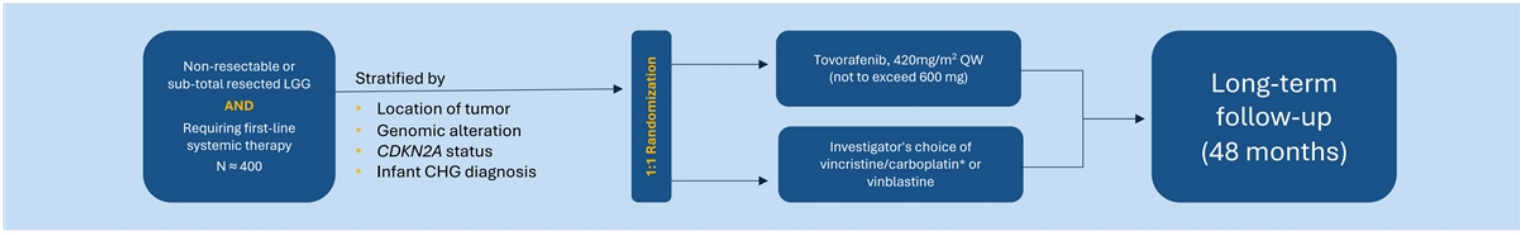
FIREFLY-2/LOGGIC Pivotal Phase 3 Trial Of Tovorafenib In Frontline pLGG

Trial Design

- Randomized, global, registrational Phase 3 trial of monotherapy tovorafenib vs SoC chemotherapy
- Eligibility: Patients aged 6 months to <25 years with LGG harboring a RAF alteration and requiring first-line systemic therapy
- Tovorafenib available as tablets and pediatric-friendly liquid suspension
- Patients who progress after stopping tovorafenib may be re-challenged
- Patients who progress in the SoC arm during or post-treatment may cross-over to receive tovorafenib

Endpoints

- **Primary endpoint: ORR based on RANO-LGG criteria, assessed by blinded independent central review**
  - **The ORR primary analysis is expected to occur ~12 months after the last patient randomized**
- Key secondary endpoints: PFS and DoR by RANO criteria, ORR by RAPNO criteria
- Other secondary endpoints: changes in neurological and visual function, safety, and tolerability
- Key exploratory objectives: QoL and health utilization measures



* COG or SIOPe-LGG regimen. Abbreviations: CHG, chiasmatic, hypothalamic glioma; DoR, duration of response; LGG, low-grade glioma; ORR, objective response rate; QoL, quality of life; QW, once weekly; SoC, standard of care.

FIRELIGHT-1

Phase 1b/2 Trials Evaluating Tovorafenib as a Combination with Pimasertib

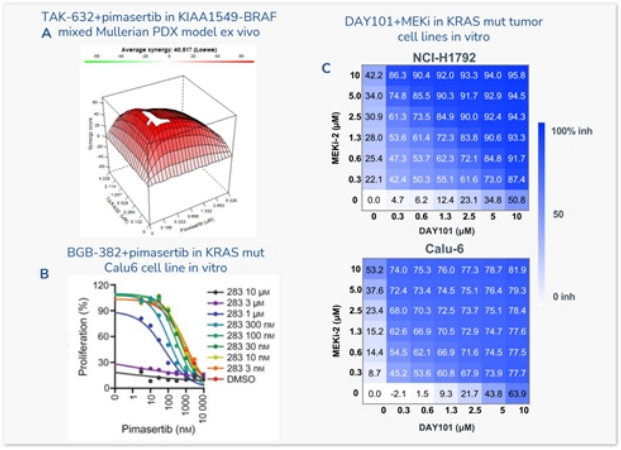
Pimasertib: Investigational Allosteric MEK1/2 Inhibitor With Demonstrated Activity In MAPK-Driven Solid Tumors

- Pimasertib is an investigational orally-bioavailable, selective, non-competitive MEK1/2 inhibitor in-licensed from Merck KGaA in February 2021
- Extensive non-clinical and clinical development work through Phase 2, including a solid tumor trial in Japan and combinations with other MOAs
- Main AEs typical for all in-class allosteric MEK inhibitors (GI, CPK elevation, skin rash, visual disturbances)
- Nearly three-fold higher CNS penetration than other MEKi inhibitors (trametinib or selumetinib)
- Pimasertib showed monotherapy clinical activity, including an improvement in median PFS versus dacarbazine in NRAS mutant melanoma
- Combination with tovorafenib and other targeted therapies may unlock the full value of pimasertib in advanced solid tumors

Sources: Pimasertib Investigator Brochure, v12, 2019; de Gooijer et al., Int J Cancer, 2018; Shaw et al., AACR LB-456, 2012; Lebbe et al., Cancers, 2020.

Vertical MAPK Pathway Inhibition With Tovorafenib And Pimasertib May Unlock Potential Synergy For Adult Solid Tumors

BRAF non-V600 mutant	KRAS or NRAS mutant
MEK → ERK	RAF/MEK/ERK; PI3K/m TOR; PI3K/m TOR
Proliferation, survival	Proliferation, survival
Type II RAFi + MEKI	Type II RAFi + MEKI
Non V600 BRAF dimers are effectively inhibited by type II RAFi , but not type I BRAFi	Targeting multiple nodes of MAPK pathway will drive deeper and more durable response



A Type II RAFi + MEKi is synergistic in BRAF fusion melanoma PDX model ex vivo (internal data)

B Sensitivity of KRAS Q61 mutant cells to pimasertib is enhanced when cells are treated with the type II BRAF inhibitor BGB-283 (Yuan et al., Mol Onc 2020)

C Tovorafenib + MEK inhibitor is synergistic in KRAS G12C and Q61 mutant tumor cells (Venetsanakos et al., 2021 AACR poster presentation)

Day One BIOPHARMACEUTICALS

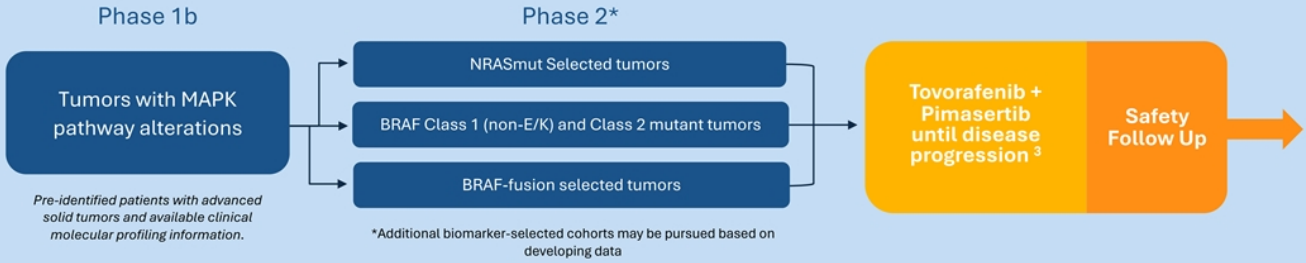
Tovorafenib / Pimasertib Combination In Solid Tumors (FIRELIGHT-1)

Trial Design[1]

- Combination dose escalation, global phase 1b/2 trial[2]
- Phase 1b, BOIN (adaptive), n = 10/cohort (approximately)
- Phase 2, Simon 2-stage, n = 25/cohort (approximately)
- Eligibility: Patients aged 12 years and older, dose escalation will be performed in advanced solid tumor patients with any MAPK alteration. Expansion cohorts will focus on indications with a potential path to accelerated approval

Endpoints

- Phase 1b: PK, PD and Safety, MTD/RP2D
- Phase 2: Efficacy (ORR, DOR)



Abbreviations: BOIN, Bayesian Optimal Interval Design; BRAF, B-Raf proto-oncogene, serine/threonine kinase; MAPK, mitogen-activated protein kinase; NRAS, neuroblastoma rat sarcoma viral oncogene. [1]Umbrella master study – DAY101-102 (main protocol) DAY101 and MAPK pathway aberration, Sub-study 1 monotherapy (DAY101-102a), Sub-study 2 MEK combo (DAY101-102b).[2]Intend to open U.S. and ex-U.S. clinical sties. [3]DAY101 + Pimasertib until disease progression, intolerable toxicity, withdrawal of consent, or death

Summary

Financial Summary: DAWN

Cash, cash equivalents and short-term investments as of March 31, 2024: $317.9 million (no debt)

PRV sale in May 2024: $108.0 million in gross proceeds

~87.4 million shares of common stock outstanding as of May 1, 2024

$ Millions	Three Months Ended 3/31/24	Three Months Ended 3/31/23
R&D Expense	$40.2	$27.8
G&A Expense	$26.6	$18.0
Net Loss	$62.4	$42.4

Projected Cash Runway into 2026

FIREFLY-1: Pivotal Phase 2 clinical trial of tovorafenib

- Data published in *Nature Medicine* and oral presentations at SNO in November 2023
- OJEMDA™ (tovorafenib) approved in the U.S. in April 2024
- Sale of PRV for $108 million in gross proceeds in May 2024

FIREFLY-2/LOGGIC: Pivotal Phase 3 clinical trial of tovorafenib in newly diagnosed pLGG

- First patient dosed in March 2023

All financial and share information is unaudited. PRV, Priority Review Voucher. As part of the PRV transaction, $8.1 million of the total consideration received from the sale of the PRV pursuant to the PRV Transfer Agreement will be paid to Viracta Therapeutics, Inc. pursuant to the Company's License Agreement with Viracta, dated December 16, 2019, as amended.

Priorities as a Commercial-Stage Company

Launch OJEMDA™ (tovorafenib)

- Expand awareness amongst physicians and establish broad coverage to enable patient access
- Establish OJEMDA as the standard of care for relapsed or refractory pLGG harboring a BRAF alteration
- Provide a positive and supportive experience when initiating OJEMDA therapy for patients and families

Advance Portfolio

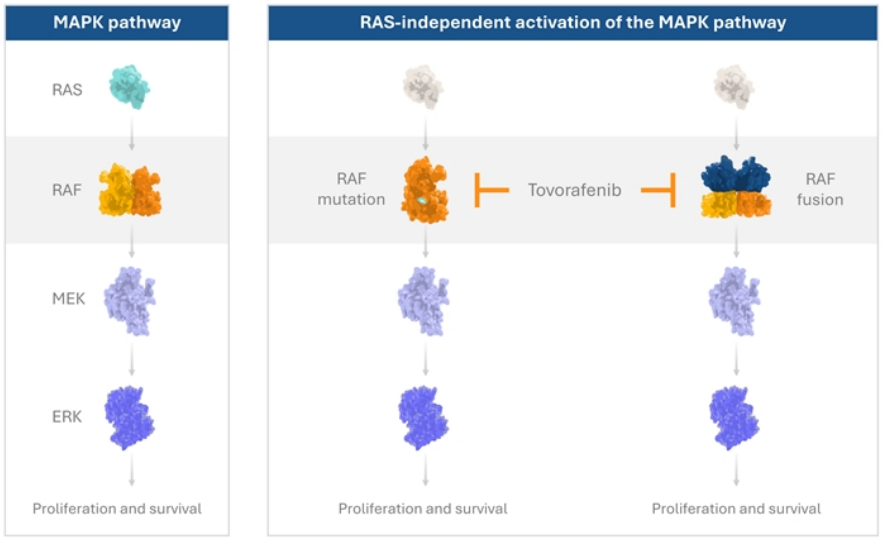
- FIREFLY-2: Study tovorafenib as a frontline therapy for treatment-naive patients with pLGG
- FIRELIGHT-1: Evaluate tovorafenib in combination with pimasertib in adolescent and adult populations
- Advance early stage VRK1 program to clinical development

Expand Pipeline

- Grow Day One into a leading, biopharmaceutical company that is the partner of choice for oncology drug development
- Explore selective partnerships as a source of capital and risk sharing
- Further invest in business development activities to expand our multiple asset portfolio for both children and adults

Appendix

Tovorafenib Inhibits Both BRAF Fusions And BRAF V600 Mutations



Tovorafenib is an investigational, oral, selective, CNS-penetrant, type II RAF inhibitor that was designed to inhibit both monomeric and dimeric RAF kinase

- Activity in tumors driven by both RAF fusions and BRAF V600E mutations
- Tablet and pediatric-friendly liquid suspension
- Once weekly dosing

Currently approved type I BRAF inhibitors are indicated for use in patients with tumors bearing BRAF V600 mutations

- Type I BRAF inhibitors cause paradoxical MAPK activation in the setting of wild-type RAF, increasing the risk of tumor growth in BRAF fusion-driven

Source: 1. Sun Y et al., Neuro Oncol. 2017; 19: 774–85; 2. Sievart AJ et al., PNAS. 2013; 110:5957-62; 3. Karajannis MA et al., Neuro Oncol 2014;16(10):1408-16.

Pivotal Phase 2 Trial Of Monotherapy Tovorafenib In Relapsed Or Progressive pLGG (FIREFLY-1)

Trial Design

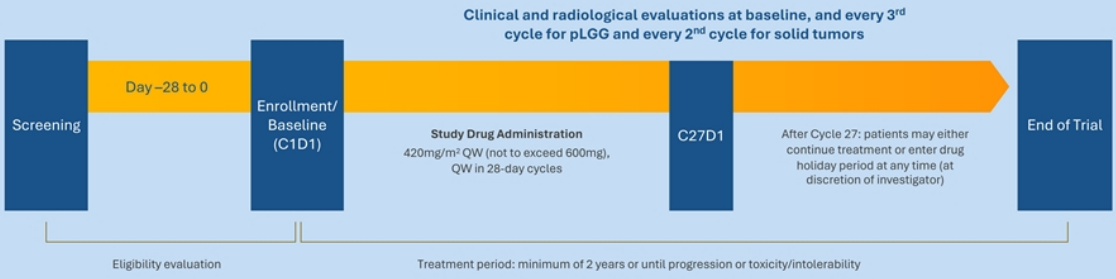
- Three arm, open-label, global registrational phase 2 trial
  - **Pivotal Arm 1 (recurrent/progressive pLGG, n=77): harboring a KIAA1549-BRAF fusion or BRAF V600E mutation**
  - Arm 2 (expanded access recurrent/progressive LGG, n=60): harboring an activating RAF alteration
  - Arm 3 (extracranial solid tumors): harboring an activating RAF fusion

Endpoints (Pivotal Arm 1)

- **Primary endpoint: ORR based on RANO-HGG[1], assessed by blinded independent central review**
- Secondary endpoints: ORR by RAPNO-LGG[2] assessed by blinded independent central review; PFS, DoR; TTR, CBR; safety
- Exploratory analyses: ORR and CBR by RANO-LGG[3] assessed by blinded independent central review

Key Inclusion Criteria

- 6 months – 25 years of age
- RAF-altered tumor
- ≥1 prior line of systemic therapy with radiographic progression
- Prior use of MAPK pathway targeted therapy was permitted



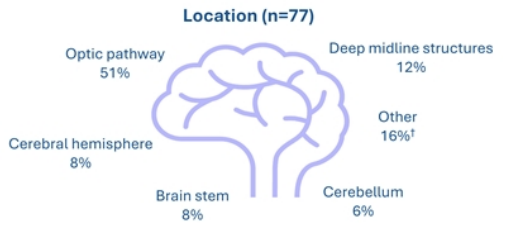
June 5, 2023 data cutoff. [1] Wen PY, et al. *J Clin Oncol*. 2010;28(11):1963-1972. [2] Fangusaro J, et al. Lancet Oncol. 2020;21(6):e305–316. [3] van den Bent MJ, et al. Lancet Oncol. 2011;12(6):583-593. Abbreviations: CBR, clinical benefit rate; IRC, independent review committee; C, cycle; D, day; LGG, low-grade glioma; ORR, objective response rate; PFS, progression-free survival; DoR, duration of response; QW, once weekly; TTR, time to response; RANO, Response Assessment in Neuro-Oncology; RAPNO, Response Assessment in Pediatric Neuro-Oncology; MAPK, mitogen-activated protein kinase. For more information, please refer to NCT04775485

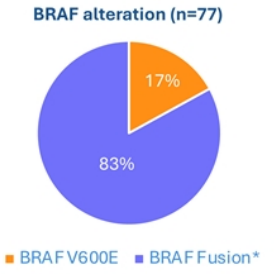
Data from Pivotal Phase 2 FIREFLY-1 Trial

June 5, 2023 data cutoff

FIREFLY-1 Baseline Patient Characteristics

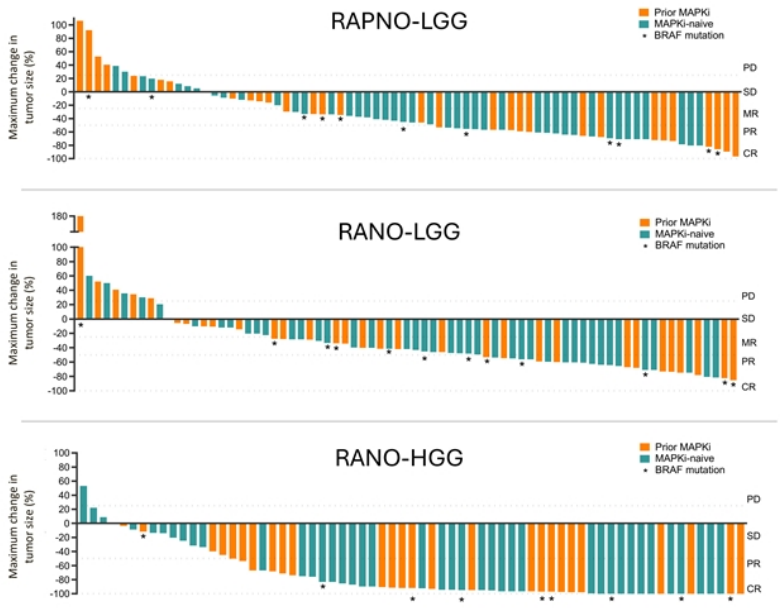
Characteristic	Arm 1 (n=77)
Median age, years (range)	8 (2-21)
Sex, n (%)	
Male	40 (52)
Female	37 (48)
Race, n (%)	
White	41 (53)
Asian	5 (6)
Black	2 (3)
Multiple	3 (4)
Other	6 (8)
Not specified	20 (26)
Number of lines of prior systemic therapy	
Median (range)	3 (1-9)
1, n (%)	17 (22)
2, n (%)	21 (27)
≥3, n (%)	39 (51)
Prior MAPK pathway targeted therapy, n (%)	
Prior MEK inhibitor	43 (56)
Prior BRAF inhibitor	8* (10)
Prior BRAF and MEK inhibitors‡	5 (7)
Any MAPK inhibitor	46 (60)





June 5, 2023 data cutoff. *Includes 6 patients with BRAF duplication and 2 with BRAF rearrangement per fluorescence in situ hybridization or in situ hybridization. †Includes tumors that were extending into multiple regions of the brain, leptomeningeal disease, and/or spinal disease. ‡The 5 patients that had previously received both a MEK inhibitor and also a BRAF inhibitor are recorded in both the "Prior MEK inhibitor" and "Prior BRAF inhibitor" groups. MAPK, mitogen-activated protein kinase.

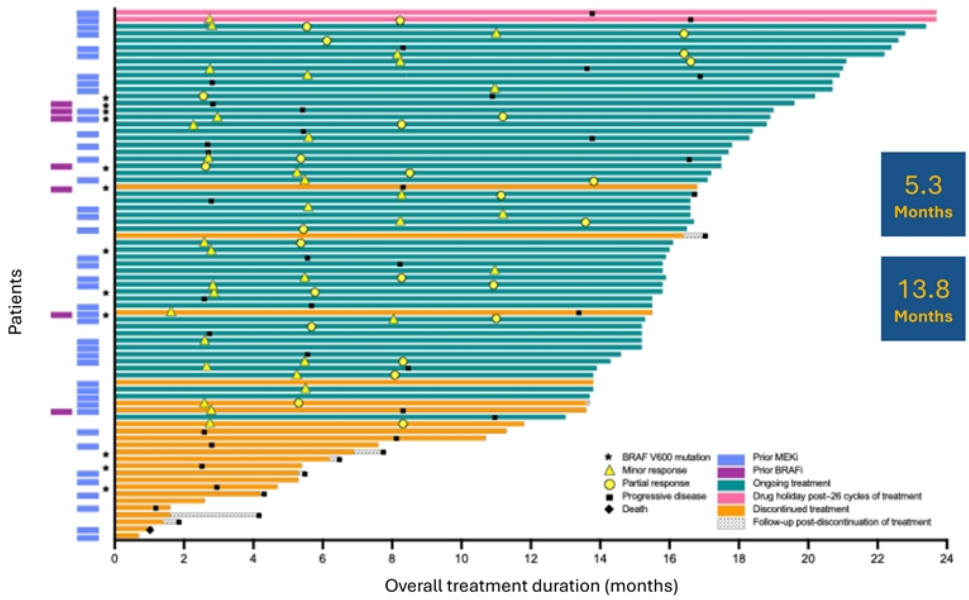
Tumor Response To Tovorafenib Using RAPNO-LGG, RANO-LGG and RANO-HGG



Response (IRC)	RAPNO-LGG n=76	RANO-LGG N=76	RANO-HGG N=69
ORR,* n (%)	**39 (51)**	**40 (53)**	**46 (67)**
95% CI	40-63	41-64	54-78
CBR,* n (%)			
SD of any length of time	62 (82)	63 (83)	64 (93)
SD ≥12 months	43 (57)	46 (61)	54 (78)
BOR,* n (%)			
CR	0	0	12 (17)
PR	28 (37)	20 (26)	34 (49)
MR	11 (14)	20 (26)	n/a
SD	23 (30)	23 (30)	18 (26)
SD <12 months	19 (25)	17 (22)	10 (14)
SD ≥12 months	4 (5)	6 (8)	8 (12)
PD	13 (17)	11 (14)	4 (6)
NE	1 (1)	2 (3)	1 (1)
Median DOR, months	**13.8**	**14.4**	**16.6**
95% CI	11.3-NR	11.0-NR	11.6-NR
Median TTR, months	**5.3**	**5.5**	**3.0**
Range	1.6-11.2	1.6-11.3	2.6-16.6

June 5, 2023 data cutoff. BOR, best overall response; CBR, clinical benefit rate; CI, confidence interval; CR, complete response; DOR, duration of response; HGG, high-grade glioma; IRC, independent radiology review committee; LGG, low-grade glioma; MR, minor response; n/a, not applicable; NE, not evaluable; NR, not reached; ORR, overall response rate; PD, progressive disease; PR, partial response; RANO, Response Assessment in Neuro-Oncology; RAPNO, Response Assessment in Pediatric Neuro-Oncology; SD, stable disease; TTR, time to response. * ORR, CBR and BOR for RAPNO-LGG and RANO-LGG included MRs.

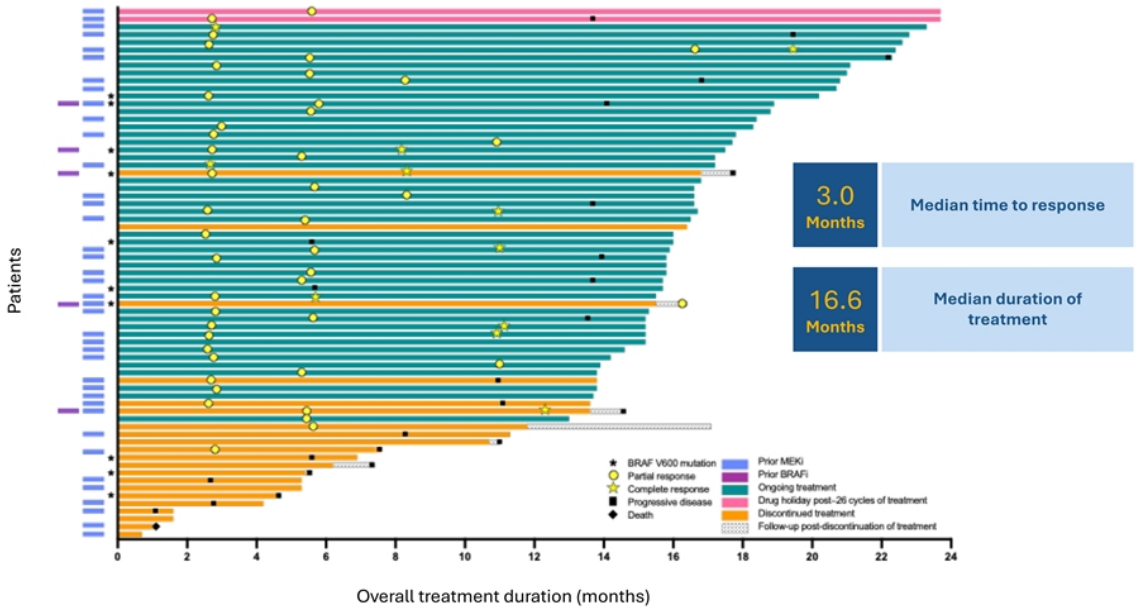
Duration Of Tovorafenib Therapy For All Patients With RAPNO-LGG Evaluable Lesions



5.3 Months — Median time to response

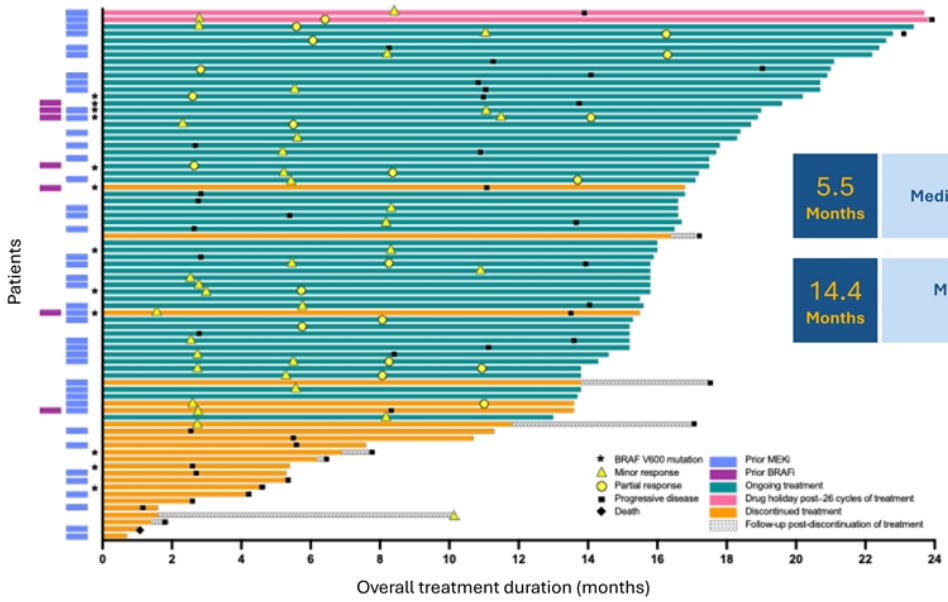
13.8 Months — Median duration of treatment

Duration Of Tovorafenib Therapy For All Patients With RANO-HGG Evaluable Lesions



June 5, 2023 data cutoff.

Duration Of Tovorafenib Therapy For All Patients With RANO-LGG Evaluable Lesions



5.5 Months — Median time to response

14.4 Months — Median duration of treatment

Tumor Response To Tovorafenib Across Three Assessment Criteria Were Consistent Across BRAF Fusion And Mutation Patients, and Patients With Prior MAPK Treatment

	RAPNO-LGG[2]		RANO-LGG[3,4]		RANO-HGG[1]	
Response (IRC)	n		n		n	
ORR,* n (%)	**76**	**39 (51)**	**76**	**40 (53)**	**69**	**46 (67)**
BRAF fusion	64	33 (52)	64	33 (52)	59	41 (69)
BRAF mutation	12	6 (50)	12	7 (58)	10	5 (50)
Prior MAPKi	45	22 (49)	45	23 (51)	41	29 (71)
MAPKi-naive	31	17 (55)	31	17 (55)	28	17 (61)
CBR,* n (%) (SD of any length of time)	**76**	**62 (82)**	**76**	**63 (83)**	**69**	**64 (93)**
BRAF fusion	64	53 (83)	64	53 (83)	59	55 (93)
BRAF mutation	12	9 (75)	12	10 (83)	10	9 (90)
Prior MAPKi	45	38 (84)	45	38 (84)	41	37 (90)
MAPKi-naive	31	24 (77)	31	25 (81)	28	27 (96)
CBR,* n (%) (SD ≥12 months)	**76**	**43 (57)**	**76**	**46 (61)**	**69**	**54 (78)**
BRAF fusion	64	37 (58)	64	39 (61)	59	49 (83)
BRAF mutation	12	6 (50)	12	7 (58)	10	5 (50)
Prior MAPKi	45	25 (56)	45	26 (58)	41	33 (80)
MAPKi-naive	31	18 (58)	31	20 (65)	28	21 (75)
Median DOR, months (95% CI)**	**39**	**13.8 (11.3-NR)**	**40**	**14.4 (11.0-NR)**	**46**	**16.6 (11.6-NR)**
BRAF fusion	33	13.8 (11.3-NR)	33	16.3 (11.0-NR)	41	16.8 (11.6-NR)
BRAF mutation	6	NR (8.4-NR)	7	12.0 (8.4-NR)	5	15.1 (8.3-NR)
Prior MAPKi	22	13.8 (11.3-NR)	23	12.0 (8.5-NR)	29	15.1 (9.0-16.8)
MAPKi-naive	17	NR (8.4-NR)	17	16.3 (8.4-NR)	17	NR (11.6-NR)

June 5, 2023 data cutoff. [1] Fangusaro J, et al. *Lancet Oncol.* 2020;21(6):e305–316. [2] Fangusaro J, et al. *Lancet Oncol.* 2020;21(6):e305–316. [3] van den Bent MJ, et al. *Lancet Oncol.* 2011;12(6):583-593. 4. Wen PY, et al. *J. Clin Oncol.* 2017;35(21),2439-2449. * ORR, CBR for RAPNO-LGG and RANO-LGG included MRs. ** the 95% CI were calculated using Kaplan-Meier method.

Tovorafenib Safety Data (n=137)

Preferred Term, n (%)	TEAEs		TRAEs	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Any AE	137 (100)	86 (63)	134 (98)	58 (42)
Hair color changes	104 (76)	0	104 (76)	0
Anemia	81 (59)	15 (11)	67 (49)	14 (10)
Elevated CPK	80 (58)	16 (12)	77 (56)	16 (12)
Fatigue	76 (55)	6 (4)	60 (44)	6 (4)
Vomiting	68 (50)	6 (4)	28 (20)	3 (2)
Hypophosphatemia	64 (47)	0	48 (35)	0
Headache	61 (45)	2 (1)	29 (21)	0
Maculo-papular rash	60 (44)	11 (8)	56 (41)	11 (8)
Pyrexia	53 (39)	5 (4)	17 (12)	1 (1)
Dry skin	49 (36)	0	45 (33)	0
Elevated LDH	48 (35)	0	42 (31)	0
Increased AST	47 (34)	4 (3)	41 (30)	4 (3)
Constipation	45 (33)	0	31 (23)	0
Nausea	45 (33)	0	25 (18)	0
Upper RTI	43 (31)	2 (1)	2 (1)	0
Dermatitis acneiform	42 (31)	1 (1)	41 (30)	1 (1)
Epistaxis	42 (31)	1 (1)	27 (20)	0
Decreased appetite	39 (28)	5 (4)	28 (20)	4 (3)
Paronychia	36 (26)	2 (1)	32 (23)	2 (1)
Pruritus	35 (26)	1 (1)	32 (23)	1 (1)
COVID-19	34 (25)	0	0	0

- The most common reasons for discontinuation were tumor hemorrhage (3 patients) and decrease in growth velocity (2 patients)
- 33 patients (24%) had TRAEs leading to dose reduction; 50 patients (37%) had TRAEs leading to dose interruption
- Median duration of dose interruption was 2 weeks
- 9 patients (7%) had TRAEs leading to discontinuation

June 5, 2023 data cutoff. Treatment-emergent AEs ≥25% any grade in arms 1 & 2. AE, adverse event; ALT, Alanine transaminase; AST, aspartate aminotransferase; COVID-19, Coronavirus disease 2019; CPK, creatine phosphokinase; LDH, lactate dehydrogenase; RTI, respiratory tract infection; TEAEs, treatment-emergent adverse events; TRAEs, treatment-related adverse events.